

UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER REQUEST DATE
09/750,022 7/7/05

FIRST NAMED APPLICANT
INDU J. ISAACS

ATTORNEY DOCKET NO.
016777/0454

Title: GLP-2 FORMULATIONS

Art Unit Paper Number

Correspondence Address:

MICHELE M. SIMKIN
FOLEY & LARDNER
3000 K ST. N.W. STE. 500
WASHINGTON, D.C. 20007

Licensee under 35 U.S.C. 184 is hereby granted to file in any foreign country a patent application and any amendments thereto corresponding to the subject matter of this U.S. application identified above and/or any material accompanying the petition. This license is conditioned upon modification of any applicable secrecy order and is subject to revocation without notice.

License Number: 536,728

Grant Date: 26-Jul-06

This license is granted retroactively to the date(s) and the country(s) indicated on the attached decision.

Approved:


for Commissioner of Patents and Trademark

This license empowers the filing, the causation and the authorization of the filing of a foreign application or applications on the subject matter identified above, subsequent forwarding of all duplicate and formal papers and the prosecution of such application or applications.

This license does not empower the filing of any applications, amendments, supplements or continuances originating in this country which disclose inventions, modifications, or variations not disclosed in the subject matter identified above.

This license is to be retained by the licensee and may be used at anytime on or after the date thereof. This license is not retroactive unless specifically indicated.

The grant of this license does not in any way lessen the responsibility of the licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations, especially with respect to certain countries, of other agencies, particularly the Office of Foreign Assets Control, Department of the Treasury; Office of Munitions Control, Department of State (with respect to Arms, Munitions and Implements of War); the Bureau of Trade Regulation, Office of Export Administration, Department of Commerce; and the Department of Energy.

LICENSE FOR FOREIGN FILING

[Title 35, United States Code (1952) Sections 184, 185, 186]



UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

Petitioner: ISAACS :DECISION ON REQUEST
Petition No.: 09/750,022 :UNDER 37 CFR 5.25
Petition Filing Date: 07 July 2005
Docket No.: 016777/0454

Title: GLP-2 FORMULATIONS

This is a decision on the petition for retroactive foreign filing license.

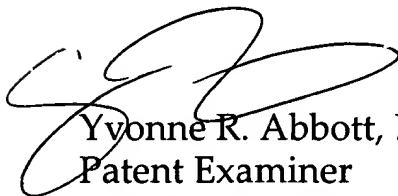
It has been determined that a retroactive license for foreign filing under 35 U.S.C. 184 be granted with respect to the filing(s) listed below. The petition complies with 37 C.F.R. 5.25 in that there is an adequate showing that the subject matter in question was not under secrecy order, that the license was diligently sought, and that the material was filed abroad without the required license under 37 C.F.R 5.11 through error and without deceptive intent.

Foreign Filing Location

United Kingdom

Date

30 December 1999


Yvonne R. Abbott, Esq.
Patent Examiner
Licensing & Review
(571) 272-6896

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MAR 23 2006

Atty. Dkt. No. 016777-0454

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Indu J. ISAACS
 Title: GLP-2 FORMULATIONS
 Appl. No.: 09/750,022
 Filing Date: 12/29/2000
 Examiner: Chih Min Kam
 Art Unit: 1653

CERTIFICATE OF FACSIMILE TRANSMISSION
 I hereby certify that this paper is being facsimile transmitted to the
 United States Patent and Trademark Office, Alexandria, Virginia
 on the date below.

Amy D. Mason
 (Printed Name)
Amy D. Mason
 (Signature)
March 23, 2006
 (Date of Deposit)

TRANSMITTAL

Mail Stop Petitions
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

Sir,

Transmitted herewith are the following documents:

- [X] Renewed Petition for Retroactive License for Filing in a Foreign Country Under 37
 CFR § 5.25
- [X] Declaration of Mary B. Springings
- [X] Applicant hereby petitions for an extension of time under 37 C.F.R. §1.136(a) for the
 total number of months checked below:

[] Extension for response filed within the first month:	\$120.00	\$0.00
[X] Extension for response filed within the second month:	\$450.00	\$450.00
[] Extension for response filed within the third month:	\$1,020.00	\$0.00
[] Extension for response filed within the fourth month:	\$1,590.00	\$0.00
[] Extension for response filed within the fifth month:	\$2,160.00	\$0.00
EXTENSION FEE TOTAL:		\$450.00
[] Small Entity Fees Apply (subtract 1/3 of above):		\$0.00
TOTAL FEE:		\$450.00

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458.88 OP

WASH_1572515.1

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Atty. Dkt. No. 016777-0454

A credit card payment form in the amount of \$450.00 is enclosed.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

If any extensions of time are needed for timely acceptance of papers submitted herewith, applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Please direct all correspondence to the undersigned attorney or agent at the address indicated below.

Respectfully submitted,

Date March 23, 2006

By Courtenay C. Brinckerhoff

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 295-4094
Facsimile: (202) 672-5399

Courtenay C. Brinckerhoff
Attorney for Applicant
Registration No. 37,288



Attorney Docket No.: 016777/0454

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Indu J. ISAACS
Title: GLP-2 FORMULATIONS
Appl. No.: 09/750,022
Filing Date: 12/29/2000
Examiner: Chih Min KAM
Art Unit: 1653

**PETITION FOR RETROACTIVE LICENSE FOR FILING
IN A FOREIGN COUNTRY UNDER 37 CFR § 5.25**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicant hereby petitions for a retroactive license for foreign filing of United Kingdom Provisional Patent Application No. 9930882.7, filed on December 30, 1999. The referenced U.S. application claims priority of the United Kingdom application. A copy of United Kingdom Provisional Patent Application No. 9930882.7 is attached.

**I. Materials Required for Grant of a Petition
for a Retroactive Foreign Filing License**

In accordance with 37 C.F.R. §5.13 and 37 CFR §5.25, a grantable petition requires a legible copy of the material upon which the license is desired and the following items:

- (1) A listing of the foreign countries in which the unlicensed material was filed;
- (2) The dates on which the material was filed;
- (3) A verified statement containing:

(i) An averment that the subject matter in question was not under a secrecy order at the time it was filed abroad, and that it is not currently under a secrecy order;

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(ii) A showing that the license has been diligently sought after discovery of the proscribed foreign filing;

(iii) An explanation of why the material was filed abroad through error and without deceptive intent without the required license under 37 C.F.R. § 5.11 having first been obtained; and

(4) The required fee under 37 C.F.R. §1.17(h).

II. Applicant's Information in Support of the Petition

A. Information Related to Requirements (1), (2), and 3(i), Above

In support of this petition, Applicant submit a copy of United Kingdom Provisional Patent Application number 9930882.7, filed on December 30, 1999, and the following information:

(1) The unlicensed material was filed in the United Kingdom.

(2) The material was filed on December 30, 1999.

(3) Applicant hereby states that the subject matter in question was not under a secrecy order at the time it was filed in the United Kingdom, and that it is not currently under a secrecy order.

B. Information Related to Requirement 3(ii), Above; The License is Being Diligently Sought After Discovery of the Proscribed Foreign Filing

In support of this statement, Applicant notes that U.S. Application No. 09/750,022, containing the same subject matter as the United Kingdom application, was filed on December 29, 2000, claiming priority of United Kingdom Provisional Patent Application No. 9930882.7. The U.S. application was granted a foreign filing license on February 15, 2001. Furthermore, Applicant also notes that International Application number PCT/US00/35512, claiming priority to United Kingdom Provisional Patent Application number 9930882.7, was filed on December 29, 2000, and was published under International Publication number WO 01/49314.

In June of 2005, during due diligence of intellectual property owned by the assignee of the United Kingdom application by another party, Applicant and Applicant's representative discovered that the application was filed in the United Kingdom without benefit of the required license. Applicant is filing the current petition promptly after learning that the required license was not obtained.

C. The Material was Filed Abroad Through Error and Without Deceptive Intent, Without the Required License Under 37 C.F.R. § 5.11 Having First Been Obtained

The material was filed abroad due to the fact that the exact inventorship of the subject matter had not yet been confirmed, and the United Kingdom does not require the names of inventors for filing a provisional application. Instructions for filing the UK application were provided by a Canadian patent attorney employed by the assignee of the UK application. The filing of the application in the United Kingdom without the required license under 37 C.F.R. §5.11 was an error, and was made without deceptive intent.

D. Submission of the Required Fee

Applicant submits with this petition the required fee under 37 C.F.R. §1.17(h) in the form of a check in the amount of \$130.00.

Based on the foregoing, Applicant respectfully requests approval of this petition.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date June 27, 2005

By Michele M. Simkin

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5538
Facsimile: (202) 672-5399

Michele M. Simkin
Attorney for Applicant
Registration No. 34,717

MAR 23 2006

Att. Dkt. No. 016777-8454

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Indu J. ISAACS
Title: GLP-2 FORMULATIONS
Appl. No.: 09/750,022
Filing Date: 12/29/2000
Examiner: Chih Min Kam
Art Unit: 1653

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF MARY B. SPRIGINGS

The undersigned, Mary B. Sprigings, does hereby declare and state as follows:

1. I am a Canadian attorney called to the Law Society of Upper Canada in Ontario. I am also a registered Canadian Patent Agent and I am registered before the U.S. Patent Office as a foreign patent attorney (Reg. No. 40,292).
2. I am a former employee of the Assignee of the captioned application, NPS Allelix Corp., an Ontario corporation.
3. I was employed by the Assignee in December of 1999 when the subject matter of the captioned application was filed in a U.K. application without first obtaining a foreign filing license from the U.S. Commissioner for Patents.
4. I was involved in the decision to file the U.K. application, and have personal knowledge about the facts surrounding that decision.
5. The error in filing the subject matter of the captioned application in the U.K. without first obtaining a U.S. foreign filing license was made without deceptive intent. I was

Atty. Dkt. No. 016777-0454

Appln. No. 09/750,022

not aware of the requirement of U.S. law that a foreign filing license must be obtained before a patent application can be filed abroad on any invention that was made in the United States.

6. The invention resulted from work done by employees of the Assignee and persons under a contract for hire. At the time, it was unclear who the inventors were and where the invention had taken place. As a result, because we were unable to determine that information in time for filing, we decided to file the application in the U.K., where inventorship need not be determined prior to filing. As such, the subject matter of the captioned application was filed in the U.K. without first obtaining a U.S. foreign filing license, without deceptive intent.

7. I am no longer employed by the Assignee, and do not have any documents relating to the decision to file the subject matter of the captioned application in the U.K. Moreover, I am informed by the Assignee that its files for this matter do not contain any documents relating to the decision to file in the U.K. other than the attached letter instructing the U.K. associate to file the application in the U.K. The lack of documentation is consistent with my recollection that I did not make any written memoranda to the file regarding this decision.

8. The attached letter instructs the U.K. associate to file the subject matter of the captioned application in the U.K. by December 31, 1999. I prepared the letter, and it bears my signature.

9. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and, further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such a willful false statement may jeopardize the validity of the application or any patent issuing thereon.

Mar 21/06

Date

Mary B. Springings

Mary B. Springings

WASH_1660825.3

MAR 23 2006

**Urquhart-Dykes & Lord**

European Patent Attorneys

Chartered Patent Attorneys

Registered Trade Mark Attorneys

European Trade Mark Attorneys

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1 Alexandra Road
Swansea
Wales
GB - SA1 5ED

Telephone : +44 (0) 1792 494322
Facsimile : +44 (0) 1792 458244
E-mail : mail@udlaw.demon.co.uk

FAXED

Ms Mary B Sprigings
Allelix Biopharmaceuticals Inc.
6850 Goreway Drive
Mississauga
Ontario
CANADA L4V 1V7

Your ref: B184UK Prov
Our ref: GMD/AL/P46555

BY FACSIMILE
30 December 1999

Dear Mary,

New UK Patent Filing - GLP-2 Formulation
NPS Allelix Corp.

file

Thank you for your faxed letter of 29th December 1999.

I confirm that this new UK provisional application is being filed today (30th December 1999). The application is being filed in the name of NPS Allelix Corp. as instructed, using the Goreway Drive address. If the Goreway Drive is not correct for NPS Allelix Corp. it should be relatively straightforward to correct in due course. An official filing receipt confirming the application date and indicating the application number allotted will be forwarded to you in the next few weeks.

Following our discussion last week concerning the situation in respect of clinical trials, essentially, what matters in Europe is what is available to any members of the public. Phase I clinical trials would, in my view, be most unlikely to have had any details made available to the public and phase II trials have not yet commenced.

Thank you for entrusting us with this new application; best wishes for a happy new year.

Yours sincerely,


Hedley W. Austin

Partners
William Orr Senior Partner
Peter Wharton Managing Partner
Philip Archer
Laurence Ben-Nathan

Hedley Austin*
Stewart Gibson
Robin Browne
Simon Belcher

Mark Green
Mark Davies*
Alison Simpson
Neil Pawlyn

Simon Raynor
Martin Vinsome
* Resident Swansea

Associated in Swansea by
Antony Gallafent
Karen Cawdell
Alison Gallafent
Clare Salisbury

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
09/750,022	07-Jul-05	INDU J. ISAACS	016777/0454

Title: GLP-2 FORMULATIONS

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Art Unit	Paper Number

Correspondence Address:

MICHELE M. SIMKIN

FOLEY & LARDNER

3000 K ST. N.W. STE. 500

WASHINGTON, D.C. 20007

PATENT & TRADEMARK OFFICE
MAILED

NOV 25 2005

LICENSING & REVIEW

Please find attached a communication from the Examiner regarding the
Petition for Retroactive License under 37 CFR 5.25.



UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

In re: ISAACS :DECISION ON REQUEST
Petition No.: 09/750,022 :UNDER 37 CFR 5.25
Petition Filing date: 07 July 2005
Docket No.: 016777/0454

Title: GLP-2 FORMULATIONS

This is a decision on the petition filed September 5, 2001 for retroactive foreign filing license.

Decision: Denied

37 CFR 5.25(a) requires the following:

1. A listing of each of the foreign countries in which the unlicensed patent application material was filed,
2. The dates on which the material was filed in each country,
3. A verified statement (oath or declaration) containing:
 - i. An averment that the subject matter in question was not under a secrecy order at the time it was filed abroad, and that it is not currently under a secrecy order,
 - ii. A showing that the license has been diligently sought after discovery of the proscribed foreign filing, and
 - iii. An explanation of why the material was filed abroad through error and without deceptive intent without the required license under § 5.11 first having been obtained, and
4. The required fee (§ 1.17(h)).

The petition is Denied at this time in that the petition is defective since the requirements set forth in 37 C.F.R. 5.25(a) (3) (iii) have not been met.

There appears to be no error as to why the material was first filed abroad, and no qualified declaration of the facts surrounding the foreign filing.

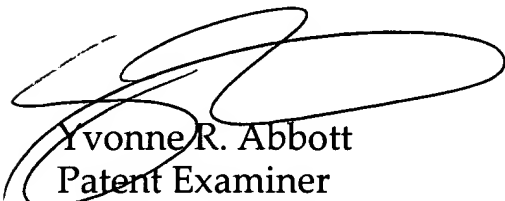
Applicant's representative (Simkin) states (Petition, ¶ C) that "the material was filed abroad due to the fact that the exact inventorship of the subject matter had not yet been confirmed, and the United Kingdom does not require the names of inventors for filing a provisional application". It appears that it was merely reliance on UK law and not lack of knowledge of the

requirements of US laws that prevented the conducting of a thorough investigation of inventorship. Not determining inventorship until later in the prosecution process is not within the meaning of "error" as provided in 37 CFR 5.25(a)(3)(iii).

Additionally, the showing of facts as to the nature of the error should include **statements by those persons responsible for or having personal knowledge of the acts regarding filing in a foreign country** (i.e. the Canadian patent attorney who provided the foreign filing instructions (Petition, ¶ C)), and should be accompanied by copies of any necessary supporting documents such as letters of transmittal or instructions for filing. The acts, which are alleged to constitute error without deceptive intent, should cover the period leading up to and including each of the proscribed foreign filings.

The petition does not include a verified statement or declaration by one who actually filed the patent applications, or who had personal knowledge of the acts regarding filing in a foreign country through error and without deceptive intent. Although Ms. Simkin is presently of counsel, she is not considered to either have filed the applications at issue or to have personal knowledge of the acts or intent surrounding said filing, and therefore, her statement is inadequate to satisfy the requirements of 37 C.F.R. 5.25.

Accordingly, the provisions of 37 CFR 5.25 not having been fully met, the petition is DENIED, and in the absence of any response within **60 days** of the mailing date of this letter, such denial will be made final and the final action under 35 U.S.C. 185 will be taken. Extensions of time may be had under 37 C.F.R. 1.136(a).



Yvonne R. Abbott
Patent Examiner
Licensing & Review
(571) 272-6896



Attorney Docket No.: 016777/0454

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Indu J. ISAACS
Title: GLP-2 FORMULATIONS
Appl. No.: 09/750,022
Filing Date: 12/29/2000
Examiner: Chih Min KAM
Art Unit: 1653

**PETITION FOR RETROACTIVE LICENSE FOR FILING
IN A FOREIGN COUNTRY UNDER 37 CFR § 5.25**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Repln. Ref 07/15/2005 NHICHOLS 0010345400
DAH:190741 Name/Number:09750022
FC: 9204 \$130.00 CR

Applicant hereby petitions for a retroactive license for foreign filing of United Kingdom Provisional Patent Application No. 9930882.7, filed on December 30, 1999. The referenced U.S. application claims priority of the United Kingdom application. A copy of United Kingdom Provisional Patent Application No. 9930882.7 is attached.

**I. Materials Required for Grant of a Petition
for a Retroactive Foreign Filing License**

Adjustment date: 07/15/2005 NHICHOLS
06/28/2005 SDENB001 00000012 09750022
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legible copy of the material upon which the license is desired and the following items:

- (1) A listing of the foreign countries in which the unlicensed material was filed;
- (2) The dates on which the material was filed;
- (3) A verified statement containing:

(i) An averment that the subject matter in question was not under a secrecy order at the time it was filed abroad, and that it is not currently under a secrecy order.

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(ii) A showing that the license has been diligently sought after discovery of the proscribed foreign filing;

(iii) An explanation of why the material was filed abroad through error and without deceptive intent without the required license under 37 C.F.R. § 5.11 having first been obtained; and

(4) The required fee under 37 C.F.R. §1.17(h).

II. Applicant's Information in Support of the Petition

A. Information Related to Requirements (1), (2), and 3(i), Above

In support of this petition, Applicant submit a copy of United Kingdom Provisional Patent Application number 9930882.7, filed on December 30, 1999, and the following information:

- (1) The unlicensed material was filed in the United Kingdom.
- (2) The material was filed on December 30, 1999.
- (3) Applicant hereby states that the subject matter in question was not under a secrecy order at the time it was filed in the United Kingdom, and that it is not currently under a secrecy order.

B. Information Related to Requirement 3(ii), Above; The License is Being Diligently Sought After Discovery of the Proscribed Foreign Filing

In support of this statement, Applicant notes that U.S. Application No. 09/750,022, containing the same subject matter as the United Kingdom application, was filed on December 29, 2000, claiming priority of United Kingdom Provisional Patent Application No. 9930882.7. The U.S. application was granted a foreign filing license on February 15, 2001. Furthermore, Applicant also notes that International Application number PCT/US00/35512, claiming priority to United Kingdom Provisional Patent Application number 9930882.7, was filed on December 29, 2000, and was published under International Publication number WO 01/49314.

In June of 2005, during due diligence of intellectual property owned by the assignee of the United Kingdom application by another party, Applicant and Applicant's representative discovered that the application was filed in the United Kingdom without benefit of the required license. Applicant is filing the current petition promptly after learning that the required license was not obtained.

C. The Material was Filed Abroad Through Error and Without Deceptive Intent, Without the Required License Under 37 C.F.R. § 5.11 Having First Been Obtained

The material was filed abroad due to the fact that the exact inventorship of the subject matter had not yet been confirmed, and the United Kingdom does not require the names of inventors for filing a provisional application. Instructions for filing the UK application were provided by a Canadian patent attorney employed by the assignee of the UK application. The filing of the application in the United Kingdom without the required license under 37 C.F.R. §5.11 was an error, and was made without deceptive intent.

D. Submission of the Required Fee

Applicant submits with this petition the required fee under 37 C.F.R. §1.17(h) in the form of a check in the amount of \$130.00.

Based on the foregoing, Applicant respectfully requests approval of this petition.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date June 27, 2005

By Michele M. Simkin

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5538
Facsimile: (202) 672-5399

Michele M. Simkin
Attorney for Applicant
Registration No. 34,717